3. Remarks

Presently, claims 18 and 20-23 are pending with claim 18 being in independent form. Claims 1-17 and 19 have been previously cancelled.

35 U.S.C. §102

The Examiner has maintained his rejection of claims 18-20 under 35 U.S.C. §102(e1) and (e2) as assertedly anticipated by U.S. Patent Appln. Pub. No. 2002/0198147 and USPN 6,642,360, respectively. Applicants respectfully traverse.

Applicants filed a §1.131 declaration evidencing Applicants were in possession of SEQ ID NO:2 (*i.e.*, a "fully characterized antigen") prior to the earliest effective filing dates of the cited prior art references. It is well-established in Federal Circuit precedent, the *Noelle v. Lederman* decision, and the USPTO's Written Description Guidelines that when an applicant discloses a fully characterized antigen, then applicant can claim antibodies to that antigen (the written description requirement is satisfied).

The Examiner's basis for rejecting the pending claims is this: "Applicant['s] possession of a fully characterized antigen of SEQ ID NO:2 cannot be extrapolated to claims to an antibody to the antigen." Inexplicably, the Examiner's position is the exact opposite of Federal Circuit precedent, the USPTO's Written Description Guidelines, and what the *Noelle v. Lederman* decision stands for.

The law is clear and unambiguous on this issue - the court in *Noelle v. Lederman* stated:

> "Therefore, based on our past precedent, **as long as an applicant has disclosed a "*fully characterized* antigen,"** either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, **the applicant can then claim an antibody by its binding affinity to that described antigen.**" (emphasis added, 60 USPQ2d 1541, 1508 (CAFC 2004))

In the Headnotes under "Patentability/Validity – Specification – Written Description" for the *Noelle v. Lederman* case, it states:

> **"Patent claim directed to any antibody which is capable of binding to particular antigen has sufficient support in written description that discloses "fully characterized" antigens; thus if applicant has disclosed fully characterized antigen, either by structure, formula, chemical name, or physical properties, or**

by depositing protein in public depository, then applicant can claim antibody by its binding affinity to that described antigen." (*Id.*)

The *Enzo* court has addressed this very issue and relied upon the long-standing practice and policy of the USPTO:

> "For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." (*Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 970 (Fed. Cir 2002)).

The *Enzo* court adopted the USPTO Guidelines as persuasive authority for the proposition that a claim directed to "any antibody which is capable of binding to antigen X" would have sufficient support in a written description that disclosed fully characterized antigens.

The holding that Noelle did not meet the written description requirement for his claims to antibodies that bound the human sequence was due to the fact that he did not provide the human sequence – he only provided the mouse sequence. If he *had* provided the human sequence, the written description requirement would have been satisfied ("If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen." *Noelle v. Lederman* at 1515). Simply put, if you provide a fully characterized antigen, you've provided written description for antibodies that bind that antigen. It is a situation unique to antibodies – describing the antigen provides written support for antibodies to that antigen.

In contrast to Noelle, Applicants have described in their specification and have shown in their §1.131 declaration that Applicants were *in possession of a fully characterized antigen* prior to the earliest effective filing date of U.S. Patent Appln. Pub. No. 2002/0198147 and USPN 6,642,360. Because Applicants were in possession of a fully characterized antigen prior to the cited art, Applicants have met the written description requirement for antibodies that bind that antigen. It's that simple, and there is no requirement for actual reduction to practice to satisfy the written description requirement.

Furthermore, the Examiner's position is contradicted by the long-standing policies and practices of the USPTO, which directly reflect Federal Circuit precedent. The Patent Offices'

Written Description Guidelines provide Example 16: Antibodies, which fully supports Applicants position:

> "Considering that the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind antigen X were implicitly disclosed as a result of the isolation of antigen X."

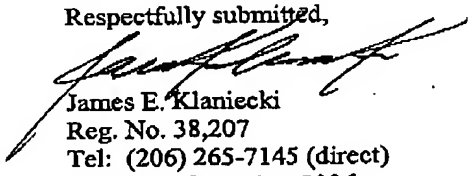
The conclusion being:

> "The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention." (Revised Interim Written Description Guidelines, http://www.uspto.gov/web/patents/guides.htm)

The Examiner is bound by the decisions of the Federal Circuit and the policies of the Patent Office. Unless the Supreme Court has overruled the specific holdings of *Noelle v. Lederman*, which it hasn't, then the Examiner must withdraw his rejection and allow the claims.

Applicants kindly request reconsideration and allowance of the claims. If any outstanding issues remain that may be easily reconciled, the Examiner is invited to telephone Applicants' representative at the number provided below.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to: Mail Stop RCE, United States Patent and Trademark Office on the date indicated below.

Signed: [signature] Date: Nov. 27, 2006